510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132796

1. Date of Submission: 08/20/2013

OCT 3 0 2013

2. Sponsor Identification

Huizhou Foryou Medical Devices Co., Ltd.
North Shangxia Rd., Dongjiang Hi-tech Industry Park, 516005, Huizhou, P. R. China.

Establishment Registration Number: 3007735241

Contact Person: Wei Lu
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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Name: SUNTOUCH® Eye Spear
Proposed Device Model: ES1001A-B, ES1001A-P, ES1001B, ES1002A-B, ES1002A-P, ES1002B, ES1003B
Proposed Device Common Name: Eye Spear

Regulatory Information:
Classification Name: Sponge, Ophthalmic;
Classification: II;
Product Code: HOZ;
Regulation Number: 886.4790;
Review Panel: Ophthalmic;

Intended Use Statement:
The Eye Spears are designed to absorb fluids and remove debris from the operative field or instruments during ophthalmic surgery.

5. Predicate Device Identification

510(k) Number: K002279
Product Name: ML Eye Spear
Manufacturer: Med-Logics, Inc

6. Device Description

SUNTOUCH® Eye Spears are sterilized, single-use devices designed to absorb fluids and remove debris from the operative field or instruments during ophthalmic surgery. The Eye Spears include seven models which share same material. The models are different in size and configuration of plastic handle.

They are provided sterilized with Sterility Assurance Level (SAL) of 10^{-6}.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10: 2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin

sensitization.

ASTM F88/F88M-09, Standard Test Method for Seal Strength of Flexible Barrier Materials.

ASTM F1140-07 (Reapproved 2012), Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.

ASTM F1929-12, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

BS EN 13726-1: 2002, Test methods for primary wound dressings —Part 1: Aspects of absorbency

USP 35-NF30:2012, <85> Bacterial Endotoxins Test.

USP 35-NF30:2012, <789> Particulate Matter in Ophthalmic Solutions

And following physical properties tests were conducted: absorption capacity, release of particulates, wicking rate, pore size, dry density, pH and formaldehyde residues in aqueous extracts, mechanical strength of sponge-handle attachment, and visual inspection for rough edges. The test results demonstrated that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Product Code	HOZ	Same
Regulation Number	21 CFR 886.4790	Same
Intended Use	The Eye Spears are designed to absorb fluids and remove debris from the operative field or instruments during ophthalmic surgery.	Same
Configuration	Expansive sponge and plastic handle	Same
Performance	Absorbency tested per BS EN 13726-1 Microscopic Particle Count tested per USP <789>	Similar
Material	Expansive sponge: PVA	Same
	Handle: PP	Same
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10.	Same
Single Use	Yes	Same
Sterilization	Method: Radiation SAL: 10-6	Same
Shelf Life	5 years	Same
Label and Labeling	Meet FDA's Requirements	Same

The proposed device, SUNTOUCH® Eye Spear, is determined to be Substantially Equivalent (SE) to the predicate device(s), ML Eye Spear (K002279), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 30, 2013

Huizhou Foryou Medical Devices Co., Ltd.
c/o Ms. Diana Hong
Mid-Link Consulting Co., Ltd.
P.O. BOX 120-119,
Shanghai, 200120, China

Re: K132796
Trade/Device Name: Suntouch® Eye Spear
Regulation Number: 21 CFR 886.4790
Regulation Name: Sponge, Ophthalmic
Regulatory Class: Class II
Product Code: HOZ
Dated: August 28, 2013
Received: September 6, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132796

Device Name: Device Name: SUNTOUCH® Eye Spear

Indications for Use:

The Eye Spears are designed to absorb fluids and remove debris from the operative field or instruments during ophthalmic surgery.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center of Devices and Radiological Health (CDRH)

Leonid Livshitz -S
2013.10.24
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K132796____